

Application No. 09/665,036

Docket No. 29155/37083

**REMARKS**

This paper is filed in response to the final official action dated December 28, 2004 (hereafter, the "official action"). This paper is timely filed.

Claims 5-10, 19-23, 34, and 37-39 are pending in this application. Claim 35 has been withdrawn from consideration.

Claims 5-7, 9, 10, 19-23, and 38-39 have been rejected under 35 U.S.C. §103(a) as assertedly being obvious over Sal'kova *et al.*, Appl. Biochem. Microbiol., 17(2):219-224 (1981) ("Sal'kova"). Claims 5, 9, 10, 19-23, 34, 37, and 39 have been rejected under 35 U.S.C. §103(a) as assertedly being obvious over Archer *et al.*, J. Anim. Sci., 33(6):1327-1331 (1971) ("Archer"). Finally, claims 5, 9, 10, 19-23, 34, 37, and 39 remain rejected under 35 U.S.C. §103 as assertedly being obvious over Archer in view of McMurry, Organic Chemistry, p.385 (1992) ("McMurry").

An explicit basis for rejecting claim 8 has not been provided.

The various bases for the claim rejections are addressed below in the order presented in the official action. Reconsideration of the application, as amended and in view of the following remarks, is solicited.

**CLAIM REJECTIONS -- 35 U.S.C. §103(a)**

A *prima facie* case of obviousness must satisfy three legal requirements. *First*, there must be some suggestion or motivation, either in the references themselves, or in knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *Second*, there must be a reasonable expectation of success. *Third*, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. See M.P.E.P. §2143. These criteria have not been satisfied with respect to pending claims 5-10, 19-23, 34, and 37-39, as explained in more detail below.

**Claims 5-7, 9, 10, 19-23, and 38-39**

Claims 5-7, 9, 10, 19-23, and 38-39 have been rejected as assertedly being obvious over Sal'kova. The applicants respectfully traverse the rejection.

Sal'kova discloses substances capable of inhibiting and suppressing the oxidation of farnesene, which were isolated from the coating of an apple fruit by extraction with hexane.

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Sal'kova does not disclose or suggest any antiviral activity for the apple fruit extract. Furthermore, Sal'kova does not disclose or suggest any therapeutic use for the antioxidant substance(s). Thus, the applicants submit that Sal'kova does not disclose or suggest formulating an antiviral preparation with a *pharmaceutically acceptable carrier* to form a pharmaceutical composition, as recited by claims 5-7, 9, 10, 19-23, and 38-39.

The term "pharmaceutically acceptable carrier" requires that the carrier does not interfere with the effectiveness of the active agent being administered, as is conventionally known. Sal'kova teaches placing the extracted products in isooctane. Isooctane is not a pharmaceutically acceptable carrier because the active antioxidant constituents obtained from an apple extract were "unstable and decomposed" in an isooctane solution. *See* Sal'kova at page 222. Thus, isooctane interferes with the effectiveness of the active agent and cannot be a pharmaceutically acceptable carrier.

The examiner acknowledged that "Sal'kova did not specifically teach wherein the final product obtained from extracting the waxy layer from the apples was admixed with a pharmaceutical carrier." *See* official action at page 3. However, the examiner stated that "the term 'pharmaceutical carrier' is very broad" and can include "water or oil for example." *Id.* Thus, the examiner concluded that "[o]ne of ordinary skill in the art would have been motivated to admix the final product obtained from the extraction . . . with a carrier such as water or oil in order to dilute the samples of the extract for analysis." *Id.*

The applicants submit that Salk'ova does *not* teach or suggest admixing "the final product obtained from the extraction . . . with a carrier such as water or oil in order to dilute the samples of the extract for analysis," as asserted by the examiner. The mere fact that a reference can be modified is not sufficient to establish a *prima facie* case of obviousness. *See* M.P.E.P. §2143.01. The prior art must also suggest the desirability of the modification. *See, e.g., In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). As noted above, Sal'kova does not disclose or suggest dilution of the extract with water or oil, and this failure, if anything, suggests that such extracts not be diluted with water or oil in analyzing the farnesene antioxidant(s). Because the cited prior art document does not suggest the desirability of the modification proposed by the examiner, the rejection of claims 5-7, 9, 10, 19-23, and 38-39 as obvious over Sal'kova should be withdrawn.

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Claims 5, 9, 10, 19-23, 34, 37, and 39

Claims 5, 9, 10, 19-23, 34, 37, and 39 have been rejected as assertedly being obvious over Archer. The applicants respectfully traverse the rejection.

Archer discloses treating whole apples with an acetone solution containing Kelthane insecticide, washing the apples with potassium hydroxide in water, ethyl alcohol, or benzene, and analyzing the residual levels of the Kelthane insecticide contaminants *remaining in the apples*, including whole apples, the pomace (skins and seeds), pulp, and juice. Archer contemplates discarding the washes and analyzing the Kelthane contaminant levels remaining in the apples. Accordingly, Archer does not disclose or suggest any antiviral activity in the various washes used to remove Kelthane from any apple fruit. Furthermore, Archer does not disclose or suggest any therapeutic use for such insecticide-containing washes, beyond killing insect pests. Thus, the applicants submit that Archer does not disclose or suggest formulating an antiviral preparation with a *pharmaceutically acceptable carrier* to form a pharmaceutical composition, as recited by claims 5, 9, 10, 19-23, 34, 37, and 39.

Moreover, Archer discloses analyzing the residual Kelthane contaminant levels of plant samples (*after treatment with one of the aforementioned washes*) by three ½ hour reflux extractions with benzene. Substantial disruption of the plant cells interior to the epidermal layer occurs when such reflux extraction methods are used. Accordingly, Archer does not disclose or suggest a method wherein the plant or plant part is exposed to a solvent under conditions sufficient to solubilize materials in the cuticular and epicuticular layers of the plant, *while leaving cells and tissues internal to the epidermis substantially unaffected*, as recited by all claims. Accordingly, the rejection of claims 5, 9, 10, 19-23, 34, 37, and 39 as obvious over Archer should be withdrawn.

Additionally, the examiner acknowledged that “Archer did not specifically teach wherein the final product obtained from extracting the waxy layer from the apples was admixed with a pharmaceutical carrier.” *See* official action at page 4. However, the examiner concluded that “[o]ne of ordinary skill in the art would have been motivated to admix the final product obtained from the extraction . . . with a carrier such as water or oil in order to dilute the samples of the extract for analysis.” *Id.*

The applicants submit that Archer does *not* teach or suggest admixing “the final product obtained from the extraction . . . with a carrier such as water or oil in order to dilute

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the samples of the extract for analysis," as asserted by the examiner. The mere fact that a reference can be modified is not sufficient to establish a prima facie case of obviousness. *See* M.P.E.P. §2143.01. The prior art must also suggest the desirability of the modification. *See, e.g., In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). As noted, Archer teaches discarding the various washes used to remove a portion of the Kelthane contaminant residues and analyzing the residues remaining in the apples. Thus, one of ordinary skill in the art would not have been motivated to even try admixing any portion of the washes with water or oil. Accordingly, the cited prior art document does not suggest the desirability of the modification proposed by the examiner, and the rejection of claims 5, 9, 10, 19-23, 34, 37, and 39 as obvious over Archer should be withdrawn.

Claims 5, 9, 10, 19-23, 34, 37, and 39

Claims 5, 9, 10, 19-23, 34, 37, and 39 remain rejected as assertedly being obvious over Archer in view of McMurry. The applicants respectfully traverse the rejection.

The deficiencies of Archer have been addressed above. McMurry does not remedy any of these deficiencies. For example, McMurry does not disclose or suggest an antiviral activity for substances obtained from cuticular or epicuticular layers external to an epidermis of a plant or plant part. Furthermore, McMurry does not disclose or suggest any therapeutic use for the antioxidant substance(s). Thus, the applicants submit that McMurry, alone or in combination with Archer, does not disclose or suggest formulating an antiviral preparation with a pharmaceutically acceptable carrier to form a pharmaceutical composition, as recited by pending claims 5-10, 19-23, 34, and 36-39, as explained above.

Accordingly, the rejection of claims 5, 9, 10, 19-23, 34, 37, and 39 as being obvious over Archer in view of McMurry should be withdrawn.

**REJOINDER OF NON-ELECTED SPECIES**

The applicants respectfully request that the non-elected species of tomato be rejoined to the application in view of the above remarks.

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CONCLUSION

It is respectfully submitted that this application is now in condition for allowance. Should the examiner wish to discuss the foregoing, or any matter of form or procedure in an effort to advance this application to allowance, she is respectfully invited to contact the undersigned attorney at the indicated telephone number.

Dated: March 28, 2005

Respectfully submitted,

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